How the LGMA Metrics Align with the Produce Rule's Requirements

LGMA
CALIFORNIA LEAFY GREEN PRODUCTS
HANDLER MARKETING AGREEMENT

08.03.2016

In 2010, President Obama signed the Food Safety Modernization Act (FSMA) into law, the first major update to federal food safety laws in 70 years. A major part of FSMA is the rule titled *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, commonly called the Produce Rule. This Rule establishes - for the first time – federal rules for on-farm food safety practices that farmers of fresh produce crops must follow to reduce the risk of contamination by foodborne pathogens.

Since 2007, Leafy greens farmers and handlers in California and Arizona have been operating under the California and Arizona Leafy Greens Marketing Agreements. These industry-driven government organizations operate with oversight from state Departments of Agriculture, and use government auditors to verify that leafy greens farmers are following a set of science-based food safety standards.

The food safety practices being followed by leafy greens farmers in California and Arizona are focused on the same risk areas identified in FSMA and will comply with or exceed the requirements proposed in the Produce Rule.

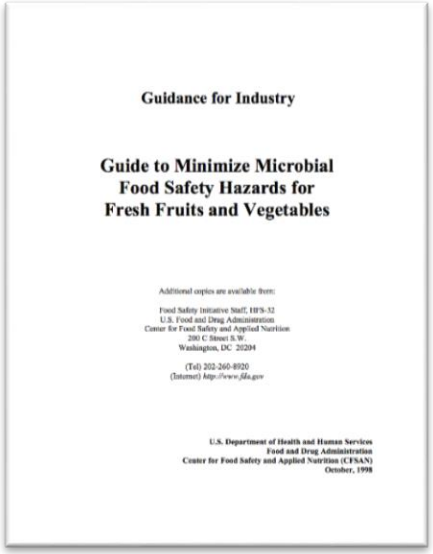
This document provides an in-depth analysis of how the standards included in the LGMA-accepted Good Agricultural Practices (the "Metrics") align with and compare to the new requirements under the Produce Rule. The document is arranged in accordance with the major sections of the Produce rule.

History of the LGMA Metrics

The California Leafy Green Products Handler Marketing Agreement (CA LGMA) exists to verify that leafy green products grown in the state of California have been produced according to an accepted set of food safety practices. The practices, created following the establishment of the LGMA in 2007, are contained in a document known as the *Commodity Specific Food Safety Guidelines for Production and Harvest of Lettuce and Leafy Greens* (or Metrics). LGMA Handler members and their growers are audited by government agricultural inspectors, using an audit that includes specific checkpoints that reflect the standards included in the Metrics.

The Metrics were developed by industry experts, food safety scientists at UC/Davis and other universities, consumer groups and other stakeholders. Regulatory officials reviewed and provided input as well. The objective was to create a set of science-based standards that were auditable and applicable to the leafy greens industry in California. The ultimate goal was to protect public health by creating a set of food safety standards that, when implemented on leafy greens farms, would prevent pathogens from being introduced into the food supply.

The creation of the LGMA Metrics followed on earlier efforts undertaken by the regulatory community and the produce industry. In fact, the basic framework for the Metrics was based on two earlier efforts. The first was guidance issued by the Food and Drug Administration in 1998, the second was guidance for leafy greens growers and processors issued by the industry in 2006.


Guidance for Industry

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

Additional copies are available from:

Food Safety Initiative Staff, HFS-32
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
October, 1998

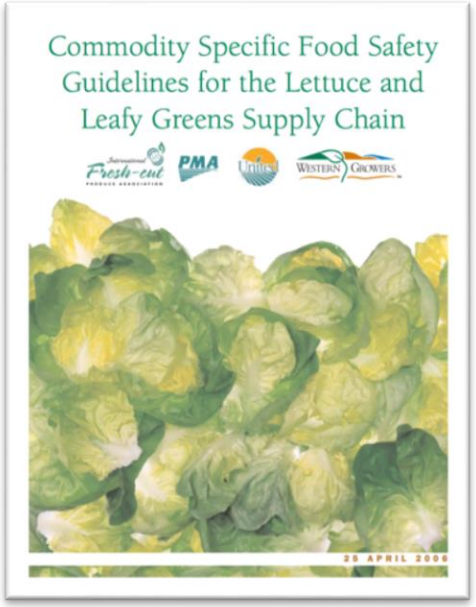
<u>1998: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.</u>

Spurred by a growing awareness of foodborne illness outbreaks associated with fresh produce, the US Department of Health and Human Services, the Food and Drug Administration and the Center for Food Safety and Applied Nutrition issued its guidance for industry in October of 1998. This first-of-its-kind document offered guidance for safe practices in five areas of risk: 1) water quality; 2) manure/municipal bio-solids; 3) worker hygiene; 4) field, facility and transport sanitation; and 5) traceback.

Guidance was provided in each area, but without specific metrics or standards. For example, in the area of Water, the guidance states that "water quality should be adequate for its intended use." Growers are then instructed to "identify the source and distribution of water used and be aware of its relative potential for being a source of pathogens" without any specific information on how to make that determination.

This was, however, the first effort by regulatory officials to offer guidance to growers designed to make produce safer in the interest of protecting public health.

2006: Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain



By the early 2000s a series of foodborne illness outbreaks traced to leafy greens led to the creation of a set of food safety guidelines by the industry. Developed over two years by the industry and by scientific and regulatory stakeholders, the voluntary guidance was released in the spring of 2006. As with the 1998 guidance document, the Guidelines were broadly written, with few auditable specifics.

2007: The LGMA-Accepted "Metrics"

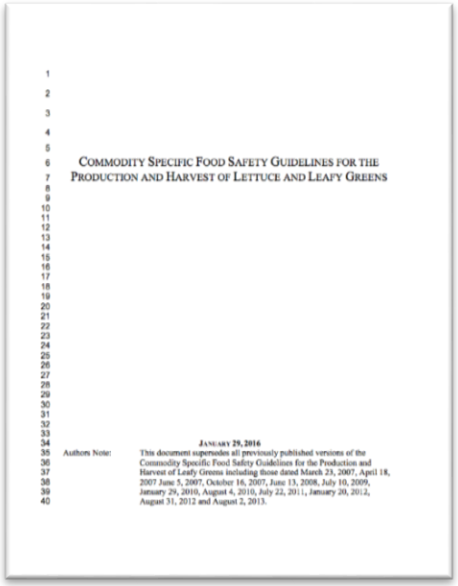
In the fall of 2006, an E. Coli outbreak traced to California-grown spinach led, tragically, to multiple deaths and over 200 illnesses in 26 states and Canada. In the wake of this outbreak, the industry worked with the California Department of Food and Agriculture (CDFA) to create the LGMA. The new organization's mandate was to verify specific food safety practices for growing, harvesting and packing leafy greens. This required the creation of specific, auditable standards that all in the industry would be required to implement (and which would be verified through government audit).

Beginning with the 1998 and 2006 guidance documents as a template, a set of specific food safety standards for leafy greens growers was developed, with measurable targets for growers to meet.

Contributors to the effort included scientists, recognized food safety experts, farmers, shippers and processors. First, a comprehensive literature review was conducted to determine a scientific basis for any given food safety standard. If the review did not identify science that could help establish a standard, the team sought support from existing or similar regulatory standards. For example, there was no scientific information on standards of foodborne pathogens in irrigation water, so the team looked to existing regulations for potable water, reclaimed water and recreational water to use as the basis for developing a standard.

If no scientific studies or regulatory standards existed, the industry sought expert opinion to help set an appropriate standard.

Unlike the earlier guidance documents, the new Metrics included very specific standards in each risk area. For example, instead of providing broad guidance on water, the Metrics included maximum levels of pathogens, testing schedule requirements and corrective actions to be taken if maximum allowable pathogen levels were exceeded. The use of raw or partially-composted manure as a soil amendment was prohibited, and specific process documentation for composted and heat-treated soil amendments was required. And three environmental assessments (pre-planting, pre-harvest and day of harvest) are required for each leafy greens field, with corrective actions that must be taken should signs of animal intrusion be identified.


COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS

JANUARY 29, 2016

Authors Note: This document supersedes all previously published versions of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens including those dated March 23, 2007, April 18, 2007 June 5, 2007, October 16, 2007, June 13, 2008, July 10, 2009, January 29, 2010, August 4, 2010, July 22, 2011, January 20, 2012, August 31, 2012 and August 2, 2013.

As new information and new science have come to light, the Metrics have been updated to reflect the changed understanding of food safety practices. While most changes have been relatively minor, there have been some major changes. In 2014, for example, standards dealing with animal intrusion were amended to ensure that growers were not

focusing solely on animals associated with E. Coli, but rather with all animal encroachment and potential contamination, regardless of pathogen.

The LGMA-accepted Metrics have been in use in the leafy greens industry since the summer of 2007, when the first government audits of LGMA member companies began to take place. Implementation of the Metrics on farms is verified through audit, and all growers who provide leafy greens to any of the LGMA's 100+ member companies is audited at least once every year.

The Food Safety Modernization ACT (FSMA) and the Produce Rule have created an environment where all growers of raw agricultural products must follow on-farm food safety practices that are very similar to those accepted through the LGMA. Leafy greens growers are committed to ensuring that the LGMA standards align with the Produce Rule – compliance with the LGMA should equal compliance with the federal Produce Rule.

The purpose of this document is to lay out the two sets of standards side by side, to identify any gaps between the two, and to begin the process of determining which changes to the LGMA Metrics need to be made in order to bring them into alignment with the Produce Rule.

Covered Produce

FDA Produce Rule	LGMA Metrics
112.1(b) …covered produce includes all of the following: (1) Fruits and vegetables such as…Belgian endive…cabbages…curly endive…dandelion leaves, fennel-Florence…kale…lettuce…spinach…Swiss chard… (2) Mixes of intact fruits and vegetables **112.2(a)** The following produce is not covered by this part: (1) Produce that is rarely consumed raw…	Leafy Greens Marketing Agreement, Article 2 (10): Leafy green products means iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard

Implications

In the Metrics but not in the Produce Rule: Lettuces by variety (iceberg, romaine, etc.), escarole, endive, spring mix, kale, arugula

In the Produce Rule but not in the Metrics: None

*All leafy green products covered by the LGMA are subject to the Produce Rule's requirements.

Training & Education

FDA Produce Rule	LGMA Metrics
112.21: What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces? (a) All personnel…must receive adequate training, as appropriate to the person's duties, upon hiring and periodically thereafter, at least once annually (b) All personnel…must have a combination of education, training and experience necessary to perform the person's assigned duties… (c) Training must be conducted in a manner that is easily understood by personnel… (d) Training must be repeated as necessary and appropriate…	Page 5 – Definition of Food Safety Professional: • Person entrusted with management level responsibility for conducting food safety assessments before food reaches consumers; requires documented training in scientific principles and a solid understanding of the principles of food safety as applied to agricultural production.
112.22: What minimum requirements apply… (a) At a minimum…must receive training that includes all of the following: (1) Principles of food hygiene and food safety; (2) Importance of health and personal hygiene for all personnel and visitors… (3) Standards…applicable to the employee's job responsibilities (b) Persons who conduct harvest activities…must also receive…all of the following: (1) Recognizing covered produce that must not be harvested… (2) Inspecting harvest containers and equipment… (3) Correcting problems with harvest containers or equipment, or reporting such problems… (c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration. **112.23**: What requirements apply regarding supervisors? You must assign or identify personnel to supervise…your operations to ensure compliance…	10.1 – The best practices include "training on proper sanitation and hygiene practices" • "Use appropriate preventive measures outlined in GAPs such as *training* in appropriate and effective hand washing, glove use and replacement, and mandatory use of sanitary field latrines to reduce and control potential contamination" • Table 5 – "If there is evidence of intrusion by animals, the production block must undergo a detailed food safety assessment by *appropriately trained* food safety Personnel" Page 5 – Definition of Food Safety Professional: Person entrusted with management level responsibility for conducting food safety assessments before food reaches consumers; requires documented training in scientific principles and a solid understanding of the principles of food safety as applied to agricultural production.

Implications

In the Metrics but not in the Produce Rule:

- Definition of food safety professional

In the Produce Rule but not in the Metrics:

- Specific training requirements are spelled out for different levels of personnel
- Training required on:
    - Food and personal hygiene
    - Importance of hygiene
    - Standards applicable to job responsibilities
- Training requirements for harvest personnel:
    - Recognizing produce not to be harvested
    - Inspecting containers/equipment
    - Correcting problems
- One supervisor must complete FDA-approved training curriculum

The LGMA will consider accepting amended language to the Metrics that more closely reflects the Rule's training requirements.

Note: The Produce Safety Alliance (PSA) – a partnership between FDA, USDA and Cornell University – has developed the training curriculum that one designated individual for each covered farm must complete. The Arizona and California LGMAs will expand their training programs to be able to offer this food safety training to industry members.

Health & Hygiene

FDA Produce Rule	LGMA Metrics
112.31: What measures must I take to prevent ill or infected persons from contaminating covered produce…? (a) You must take measures to prevent contamination…from any person with an applicable health condition… (b) The measures…must include all of the following: (1) Excluding any person from working in any operations that may result in contamination… (2) Instructing personnel to notify their supervisor(s)…if they have…an applicable health condition	10.1 – Establish a worker health practices program (i.e., an SOP) that addresses the following issues: • Workers with diarrhea disease or symptoms of other infectious disease are prohibited from handling fresh produce. • Workers with open cuts or lesions are prohibited from handling fresh produce without specific measures to prevent cross contamination of product. • Actions for employee to take in the event of injury or illness. • A policy describing procedures for handling/disposition of produce or food contact surfaces that have come into contact with blood or other body fluids
112.32: What hygienic practices must personnel use? (a) Personnel…must use hygienic practices while on duty… (b) The hygienic practices…must include all of the following practices: (1) Maintaining adequate personal cleanliness… (2) Avoiding contact with animals… (3) Washing hands thoroughly… (i) Before starting work (ii) Before putting on gloves (iii) After using the toilet (iv) Upon return to the work station after any break or absence… (v) As soon as practical after touching animals… (vi) At any other time when the hands may have become contaminated (4)…Maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so… (5) Removing or covering hand jewelry… (6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity	10.1 – This program shall establish the following practices for field and harvest employees as well as visitors: • Prior to harvest, an individual should be designated as responsible for harvesting food safety • Training on proper sanitation and hygiene practices • Requirements for workers to wash their hands before beginning or returning to work • Confinement of smoking, eating and drinking of beverages other than water to designated areas. • Prohibitions on spitting, urinating or defecating in the field • Personal item storage
112.33: What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces… (a) You must make visitors aware of policies and procedures… (b) You must make toilet and hand-washing facilities accessible to visitors	10.1 – Field and Harvest Personnel Use appropriate preventive measures outlined in GAPs such as training in appropriate and effective hand washing, glove use and replacement, and mandatory use of sanitary facilities to reduce and control potential contamination.

	Establish a written worker practices program (i.e., an SOP) that can be used to verify employee compliance with company food safety policy. This program shall establish the following practices for field and harvest employees **as well as visitors**.

Implications

In the Metrics but not in the Produce Rule:

- Nothing

In the Produce Rule but not in the Metrics:

- Specific requirements for glove sanitation and maintenance

The health and hygiene requirements included in the Rule are covered in the Metrics, with the one exception noted above.

Water

FDA Produce Rule	LGMA Metrics
112.41: All agricultural water must be safe and of adequate sanitary quality for its intended use.	4.1 – the Best Practices are: Use irrigation water and water in harvest operations that is of appropriate microbial quality for its intended use; see Table 1 and Decision Trees (1A, 1B and 1C) for specific numerical criteria. Appendix B provides the basis for these water quality metrics.
112.42: What requirements apply…? (a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems…to identify conditions that are reasonably likely to introduce…hazards…including consideration of the following: (1) The nature of each…water source (i.e. ground or surface) (2) The extent of control… (3) The degree of protection of each source… (4) Use of adjacent and nearby land (5) Likelihood of introduction of…hazards… (b) Adequately maintain all agricultural water distribution systems to the extent they are under your control… (c) Adequately maintain all agriculture water sources… (d) As necessary…implement measures reasonably necessary to reduce the potential for contamination…	4 – During the sanitary survey that is performed prior to each growing season expected microbial values and historical monitoring data should be used to evaluate the quality of the water source 4.1 – A water system description shall be prepared. This description can use maps, photographs, drawings or other means to communicate the location of permanent fixtures and the flow of the water system (including any water captured for re-use.). Permanent fixtures include wells, gates, reservoirs, valves, returns and other above ground features that make up a complete irrigation system should be documented in such a manner as to enable location in the field. Water sources and the production blocks they may serve should be documented. • Water systems that convey untreated human or animal waste must be separated from conveyances utilized to deliver irrigation water. • Perform a sanitary survey prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table 1. • Retain documentation of all test results and/or Certificates of Analysis available for inspection for a period of at least 2 years. Other Considerations for water • Evaluate irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.) for their potential to introduce, support or promote the growth of human pathogens on lettuce and leafy greens. Consider such factors as the potential for depositing soil on the crop, presence of pooled or standing water that attracts animals, etc. • When waters from various sources are combined, consider the potential for pathogen growth in the water. • For surface water sources, consider the impact of storm events on irrigation practices.

	• Use procedures for storing irrigation pipes and drip tape that reduce or eliminate potential pest infestations. • Develop procedures to provide for microbiologically safe use of irrigation pipes and drip tape if a pest infestation does occur. • Reclaimed water shall be subject to applicable state and federal regulations and standards. Use of this water for agricultural purposes must meet the most stringent standard as defined by the following: state and federal regulation or Table 1 of this document…
112.43: Treating agricultural water (a) When water is treated… (1) Any method you use (physical treatment, using a pesticide, antimicrobial pesticide, or other) …must be effective to make the water safe and of adequate sanitary quality… (2) …Deliver any treatment…in a manner to ensure the treated waters is consistently safe… (b) …Monitor any treatment…at a frequency adequate to ensure that the treated water is consistently safe…	From Table 1: Water Use If any one sample exceeds the acceptance criteria, then the water shall not be used for this purpose unless appropriate disinfectants have been added or until remedial actions have been completed and generic E. coli levels are within acceptance criteria
112.44: Specific microbial quality criteria for certain intended uses (a) …Ensure there is no detectable generic E. coli in 100 mL of age water, and do not use untreated surface water for any of these purposes: (1) Sprout irrigation (2) Applied in any manner that directly contacts covered produce during or after harvest activities… (3) Used to contact food contact surfaces, or to make ice… (4) Used for washing hands…	From Table 1: Water Use POSTHARVEST - Direct Product Contact or Food Contact Surfaces: Water that directly contacts edible portions of harvested crop, or is used on food contact surfaces, such as equipment or utensils, shall meet the Maximum Contaminant Level Goal for E. coli as specified by U.S. EPA or contain an approved disinfectant at sufficient concentration to prevent cross contamination. Microbial or physical/chemical testing shall be performed, as appropriate to the specific operation, to demonstrate that acceptance criteria have been met. Single Pass vs. Multiple Pass Systems • Single pass use – Water must have **non-detectable levels of E. coli** or breakpoint disinfectant present at point of entry • Multi-pass use – Water must have **non-detectable levels of E. coli** and/or sufficient disinfectant to ensure returned water has no detectable E. coli (minimally 1 ppm chlorine)
(b) …For water used during growing activities for covered produce using a direct water application method, the following criteria apply:	From Table 1: Water Use Foliar Applications - Whereby Edible Portions of the Crop ARE Contacted by Water

(1) A geometric mean of water samples of 126 or less CFU of generic E. coli per 100 mL of water (2) A statistical threshold value (STV) of water samples of 410 or less CCFU of generic E. coli per 100 mL of water (STV is a measure of variability of water quality distribution, derives as a model-base calculation approximating the 90th percentile using the lognormal distribution)	For any given water source (municipal, well, reclaimed water, reservoir or other surface water), samples for microbial testing shall be taken at a point as close to the point of use as practical (as determined by the sampler, to ensure the integrity of the sample, using sampling methods as prescribed in Table 1) where the water contacts the crop, so as to test both the water source and the water distribution system. In a closed water system (meaning no connection to the outside) water samples may be collected from any point within the system but are still preferred as close to point of use as practical. **No less than one sample per month per distribution system is required under these metrics** unless a system has qualified for an exemption. If there are multiple potential point-of-use sampling points in a distribution system, then samples shall be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations). <u>Acceptance Criteria</u>: ≤126 MPN (or CFU*)/100 mL (rolling geometric mean n=5) and ≤235 MPN/100mL for any single sample.
112.45: Measures to take if agricultural water does not meet the requirements of 112.41 or 112.44 (a) If…agricultural water is not safe or of adequate sanitary quality…immediately discontinue that use, and before you may use the water source and/or distribution system again…you must either: (1) Re-inspect the entire affected water system...identify any conditions that are likely to introduce…hazards, make necessary changes and take adequate measures to determine if your changes were effective and…ensure that your water meets the microbial quality criterion in 112.44; ***OR*** (2) Treat the water (112.43)	From Table 1: Water Use Remedial Actions: If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water shall not be used whereby edible portions of the crop are contacted by water until remedial actions have been completed and generic E. coli levels are within acceptance criteria: • Conduct a sanitary survey of water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s). • For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey. • Retest the water after conducting the sanitary survey and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. This sample should represent the conditions of the original water system, if feasible this test should be as close as practical to the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) shall be instituted if an explanation for the exceedance is not readily apparent. • This type of sampling program should also be instituted if an upward trend is noted in normal sampling results.
(b) If…agricultural water does not meet the microbial quality criteria required under 112.44, as soon as practicable and no later than the following year, you must discontinue that use, unless you either: (1) Apply a time interval…by:	*The LGMA Metrics do not allow for a time interval to achieve microbial die-off*

(i) Applying a time interval between the last irrigation and harvest using either: (A) A microbial die-off rate of 0.5 log per day to achieve a log reduction of the GM and STV to meet the criteria in112.44, but no greater than a maximum time interval of 4 consecutive days; or (B) An alternative microbial die-off rate…; and/or (ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the criteria in 112.44(b), and any accompanying maximum time interval or log reduction, provided you aver adequate supporting scientific data and information; or (2) Re-inspect the entire affected…water system…, make necessary changes…, determine if your changes were effective…; or (3) Treat the water…	
112.46: Testing agricultural water… (a) No requirement to test water that is subject to 112.44 when: (1) You receive water from a Public Water System… (2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement in 112.44(a), and you have public water system results or certificates, or (3) You treat water…	From Table 1: Water Use Municipal & Well Exemption: For wells and municipal water sources, if generic E. coli are below detection limits for five consecutive samples, the sampling frequency may be decreased to no less than once every 180 days and the requirements for 60 and monthly sampling are waived. This exemption is void if there is a significant source or distribution system change.
(b) You must take the following steps for each source of water used for purposes that are subject to 112.44(b): (1) Conduct initial survey to develop water quality profile… (i) The initial survey must be conducted: (A) For an untreated surface water source, by taking a minimum total of 20 samples of water over a minimum period of 2 years, but not greater than 4 years (B) For untreated ground water source, take minimum of four samples of water during the growing season or over a period of 1 year (ii) Samples …must be representative of your use…and collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile consists of the GM and the STV…You must determine the appropriate way in which the water may be used based on your MWQP. (iii) …Update the MWQP annually	Water for preharvest, direct edible portion contact shall meet or exceed microbial standards for recreational water, based on a rolling geometric mean of the five most recent samples Sampling Procedure: 100 mL sample collected aseptically at the point of use; i.e., one sprinkler head per water source for irrigation, water tap for pesticides, etc. Water utilized in preseason irrigation operations may be tested and utilized. Sampling Frequency: One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected no less than 18 hr apart and at least monthly during use from points within the distribution system.
(2) Conduct an annual survey to update the MWQP (i) …Test the water annually…analyze:	*The Metrics do not require creation of a Microbial Water Quality Profile for agricultural water.*

(A) For an untreated surface water source, a minimum of five samples per year… (B) For an untreated ground water source, a minimum of one sample per year. (ii) Samples …must be representative of your water use and collected as close in time as practicable to, but prior to, harvest. (iii) To update the WQP, calculate revised GM and STV using your current annual survey data, combined with your most recent survey data from eh proves 4 years, to make up a rolling data set of: (A) At least 20 samples for untreated surface water, and (B) At least 4 samples for untreated ground water sources. (iv) …Modify your water use…based on the revised GM and STV values… (3) If…you have reason to believe that the MWQP no longer represents the quality of your water…develop a new MWQP reflective of the time period at which you believe your MWQP changed. (i) To develop a new MWQP…calculate new GM and STV values, using current annual data combined with new data, to make up a data set of: (A) At least 20 samples of untreated surface water (B) At least four samples for untreated ground water sources (ii) Modify water use based on the new GM and STV values… (c) For untreated ground water…test the microbial quality of each source at least 4 times during the growing seasons or over a period of 1 year…If the 4 initial samples meet the microbial quality criteria of 112.44, test once annually thereafter…Resume testing at least 4 times per growing season or year if any annual test fails to meet the microbial quality criteria in 112.44(a)	
112.47: Who must perform the tests…and what methods must be used? (a) You may meet the requirements…using: (1) Test results…performed by you… (2) Data collected by 3rd parties, provided the water sources sampled…adequately represent your water sources… (b) Ag water samples must be aseptically collected and tested…	From Table 1: Water Use Test Method: FDA BAM method or any U.S. EPA approved or AOAC accredited method for quantitative monitoring of water for generic E. coli. Presence/absence testing with a similar limit of detection may be used as well.
112.48: …Water used during harvest, packing, and holding activities for covered produce… (a) …manage the water as necessary, including…water-change schedules for recirculated water…	5.1 - Due to the timing of application of water that directly contacts edible portions of lettuce/leafy greens, assure the water is of appropriate microbial quality (e.g., meets U.S. EPA microbial standards for drinking water). Test the water source periodically to demonstrate it is of appropriate microbial quality for its intended purpose (e.g., meets U.S. EPA or WHO microbial standards for

(b) …visually monitor the quality of water…for example, water used for washing in dump tanks, flumes or wash tanks, and water used for cooling... (c)…Maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation…	drinking water) or assure that it has appropriate disinfection potential as described in Table 1.
§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46? You must test the quality of water using: • The method of analysis published by the U.S. Environmental Protection Agency (EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA-821-R-09-007)," December, 2009…or • (b)(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or (2) For any other indicator of fecal contamination you may test for pursuant to § 112.49 (a), a scientifically valid method.	Table One: Water Use Test Method: FDA BAM method or any U.S. EPA approved or AOAC accredited method for quantitative monitoring of water for generic E. coli. Presence/absence testing with a similar limit of detection may be used as well.

Implications

<u>In the Metrics but not in the Produce Rule</u>:

- Water testing also required for non-foliar applications
- Preparation of a water system description and map
- Rolling geometric mean with single sample not to exceed 235 CFU/100 mL Water
- Monthly testing of all water sources (six-month exemption available for groundwater)

<u>In the Produce Rule but not in the Metrics</u>:

- Water inspection to include
  - Extent of control
  - Degree of protection
- Requires temperature monitoring during packing and handling (not applicable for leafy greens)
- For Ag water quality during/after harvest:
  - Target organism absent when making ag teas
  - Target organism absent for handwashing water (not in the Metrics, but included in the LGMA audit)
- Creation of a Microbial Water Quality Profile consisting of
  - Geometric mean

- Statistical Threshold Value of up to < 410 CFU/100 mL water
- Allows post-harvest interval of up to four days for pathogen die-off

There is significant overlap between the Metrics and the Rule. Both require testing of all "agricultural" water (foliar, in the Metrics) and water used for cleaning and sanitation. Both base the microbial testing on generic e. Coli, and use 126 mpl per 100 mL as the standard.

The Rule introduces concepts that are not part of the LGMA's Metrics, including the Microbial Water Quality Profile (MWQP) and the Statistical Threshold Value (STV). It also allows for a waiting period between application of water and shipping of product, to allow for microbial die-off. These provisions provide flexibility to growers. Since that flexibility is not available to growers under the LGMA, growers can be seen to be meeting a higher standard. Still, in order to be compliant with the Rule, the LGMA may need to consider requiring that a MWQP for each source of covered water, which can presumably be based on testing already being done under the LGMA program.

Concerns have been raised about the acceptable methods for testing water quality as stipulated by the Rule. The Membrane Filtration method identified in the Rule as the acceptable method for testing water is not considered an industry standard, and many have voiced concerns about its suitability and price. For growers who live in more rural areas transporting water samples in the relatively short period of time required for membrane filtration testing will prove problematical. And, since this is not the standard that has been used in the industry, it calls into question the use of ten years (or more) of water testing data that growers in the leafy greens industry have already collected.

The Metrics also include a more rigorous approach to microbial water testing – growers are required to test their water sources on a monthly basis (six-month exemptions can be obtained under some circumstances) whereas the rule requires four annual tests (following an initial 20) for surface waters and one annual test (following an initial five tests) for groundwater. Since most leafy greens farmers have been testing all water sources monthly since at least 2007, meeting the new federal requirements should not pose a challenge.

In evaluating whether the LGMA's water standards meet the Rule's, it will be necessary to determine how critical FDA may consider concepts like the MWQP to be to a rigorous food safety program.

112.51: What requirements apply for determining the status of a biological soil amendment of animal origin? (a) A biological soil amendment…is *treated* if it has been processed to completion to adequately reduce microorganisms in accordance with 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the teas is not untreated surface water, and the water has no detectable generic E. coli in 100 mL of water. (b) A soil amendment is *untreated* if it: (1) Has not been processed to completion in accordance with 112.54… (2) Has become contaminated after treatment; (3) Has been recombined with untreated amendments… (4) Is or contains a component that is untreated waste… (5) Is an ag tea made with materials of animal origin that contains an ag tea additive.	Definitions: Active Compost: Compost feedstock that is in the process of being rapidly decomposed and is unstable. Active compost is generating temperatures of at least 50 degrees Celsius (122 degrees Fahrenheit) during decomposition; or is releasing carbon dioxide at a rate of at least 15 milligrams per gram of compost per day, or the equivalent of oxygen uptake. Biofertilizers: Fertilizer materials/products that contain microorganisms such as bacteria, fungi, and cyanobacteria that shall promote soil biological activities. Biosolids: Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes. Green Waste: "Green Waste" means any plant material that is separated at the point of generation, contains no greater than 1.0 percent of physical contaminants by weight. Green material includes, but is not limited to, yard trimmings ("Yard Trimmings" means any wastes generated from the maintenance or alteration of public, commercial or residential landscapes including, but not limited to, yard clippings, leaves, tree trimmings, prunings, brush, and weeds), untreated wood wastes, natural fiber products, and construction and demolition wood waste. Green material does not include food material, biosolids, mixed solid waste, material processed from commingled collection, wood containing lead-based paint or wood preservative, mixed construction or mixed demolition debris. "Separated at The Point of Generation" includes material separated from the solid waste stream by the generator of that material. It may also include material from a centralized facility as long as that material was kept separate from the waste stream prior to receipt by that facility and the material was not commingled with other materials during handling. Nonsynthetic crop treatments: Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens.

	Synthetic crop treatments (chemical fertilizers): Any crop inputs that may be refined, and/or chemically synthesized and/or transformed through a chemical process (e.g. gypsum, lime, sulfur, potash, ammonium sulfate etc.). Soil amendment: Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life.
112.52: How must I handle, convey and store biological soil amendments…? (a) …Handle, convey and store …in a manner and location such that it does not become a potential source of contamination… (b) …handle, convey and store…in a manner and location that minimizes the risk of it becoming contaminated by untreated soil amendments of animal origin (c) Handle, convey and store any biological soil amendment of animal origin that you have reason to believe may have becoming contaminated as if it was untreated.	6.1 – Soil Amendments • Use soil amendment application techniques that control, reduce or eliminate likely contamination of surface water and/or edible crops being grown in adjacent fields. • Segregate equipment used for soil amendment handling, preparation, distribution, applications or use effective means of equipment sanitation before subsequent use that effectively reduce the potential for cross contamination. • Minimize the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing lettuce/leafy greens or adjacent edible crops. Segregate equipment used for soil amendment applications or use effective means of equipment sanitation before subsequent use.
112.53: …You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent…	6.1 – Soil Amendments • Do not use biosolids as a soil amendment for production of lettuce or leafy greens. • DO NOT USE raw manure or soil amendment that contain un-composted, incompletely composted animal manure and/or green waste or non-thermally treated animal manure to fields
112.54: What treatment processes are acceptable…? Each of the following…are acceptable: (a) A scientifically valid controlled physical… chemical… biological process…or a combination of …physical, chemical and/or biological processes that…satisfies the microbial standard in 112.55(a) for LM, Salmonella and E. coli 0157:H7; ***or*** (b) A scientifically valid controlled physical, chemical or biological process, or a combination…that has been validated to satisfy the microbial standard in 112.55(b) for Salmonella and fecal coliforms. Examples…include: (1) Static composting that maintains aerobic… conditions at a minimum of 131 degrees F for 3 consecutive days and is followed by adequate curing; and	Table 2: Composting Process Validation (Composted Soil Amendments containing animal manure or animal products): Enclosed or within-vessel composting: Active compost must maintain a minimum of 131 degrees F for 3 days Windrow composting: Active compost must maintain aerobic conditions for a minimum of 131 degrees F or higher for 15 days or longer, with a minimum of five turnings during this period. Aerated static pile composting:

(2) Turned composting that maintains aerobic conditions at a minimum of 131 degrees F for 15 days…with a minimum of 5 turnings, followed by adequate curing.	Active compost must be covered with at least 12 inches of insulating materials and maintain a minimum of 131 degrees F for 3 days Target Organisms: • Fecal coliforms • Salmonella spp • E. coli O157:H7 Acceptance Criteria: • Fecal coliforms <1000 MPN/gram • Salmonella: Negative or < DL (<1/ 30 grams) • E. coli O157:H7: Negative or < DL (<1/ 30 grams) Recommended Test Methods: • Fecal coliforms: 9 tube MPN • Salmonella spp: U.S. EPA Method 1682 • E. coli O157:H7: Any laboratory validated method for compost sampling. • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate. Sampling Plan: • A composite sample shall be representative and random and obtained as described in the California state regulations. • Sample may be taken by the supplier if trained by a testing laboratory or state authority • Laboratory must be certified/accredited for microbial testing by an appropriate process authority Testing Frequency: • Each lot before application to production fields. A lot is defined as a unit of production equal to or less than 5,000 cubic yards. Note: Criteria are also included in the LGMA Metrics for the following *additional* categories of soil amendments: • Soil amendments containing animal manure that have been physically heat treated or processed by other equivalent methods • Soil Amendments Not Containing Animal Manure • Nonsynthetic Crop Treatments
112.55: What Microbial standards apply to the treatment processes in 112.54?	Records must be available to document that the following criteria have been meet for each utilized lot of compost containing animal material.

(a) For LM, Salmonella and E. coli 0157:H7, the relevant standards are as follows; ***or*** (1) LM: Not detected using a method that can detect one CFU per 5-gram portion. (2) Salmonella: Not detected using a method that can detect 3 MPN per 4 grams of total solids (3) E. Coli: Not detected using a method that can detect .3 MPN per 1-gram analytical portion. (b) Salmonella species are not detected using a method that can detect 3 MPN Salmonella species per 4 grams of total solids; and less than 1,000 MPN fecal coliforms per gram of total solids.	a. Acceptance criteria Fecal coliforms: <1000 MPN/gram Salmonella: Negative per sample size of the prescribed test E. coli O157:H7: Negative per sample size of the prescribed test
112.56: Application requirements and minimum application intervals… (a) …apply the soil amendments…in accordance with the following: (1)(i) Untreated – Applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application: the application interval is RESERVED (1)(ii) Untreated – Applied in a manner that does not contact covered produce during or after application: the application interval is 0 Days (2) Treated by a scenically valid controlled physical, chemical or biological process…as per 112.54(b) – Applied in a manner that minimizes the potential for contact with covered produce during and after application: Application interval is 0 Days (3) Treated by a scientifically valid physical, chemical or biological process…in accordance with 112.54(a) – Applied in any manner: application interval is 0 Days.	Table 2: Soil Amendments Raw Manure or Not Fully Composted green waste and/or Animal Manure Containing Soil Amendments: • DO NOT USE OR APPLY Composted Soil Amendments (containing animal manure or animal products): • Must be applied >45 days before harvest. Soil amendments containing animal manure that has been physically heat treated or processed by other equivalent methods: • If the physical heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments, is validated and meets the microbial acceptance criteria outlined above, then no time interval is needed between application and harvest. • If the physical heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments is not validated but will likely significantly reduce microbial populations of human pathogens and meets microbial acceptance criteria outlined above, then a 45-day interval between application and harvest is required. Soil Amendments Not Containing Animal Manure: • If there is documentation that the amendment does not contain manure or animal products then no additional testing is required, and there is no application interval necessary From Table 3: Nonsynthetic Crop Treatments:

	• If the physical, chemical and/or biological treatment process used to render the crop input safe for application to edible crops is validated and meets that microbial acceptance criteria outlined above, no time interval is needed between application and harvest. • If the physical, chemical and/or biological treatment process used to render the crop input safe for application to edible crops is not validated yet meets the microbial acceptance criteria outlined above, a 45-day time interval between application and harvest is required.

Implications

In the Metrics but not in the Produce Rule:

- Use of biosolids, raw manure or soil amendments that contain un-composted or incompletely composted animal manure and/or green waste is not allowed.
- Composted soil amendments require harvest interval of $>$ 45 days.

In the Produce Rule but not in the Metrics:

- Requires testing and analysis for Listeria

The FDA intends to reduce the risk of contamination from biological soil amendments of animal origin by regulating types of treatment, methods of application, and time intervals between the application of a biological soil amendment of animal origin and crop harvest. FDA has announced its intention to conduct a thorough risk assessment (five to ten years) before finalizing the mandatory harvest intervals. FDA has indicated that it does not object to growers following the existing USDA National Organic Standard in the interim.

Once the FDA completes its process of evaluating soil amendment standards and adding them to the Produce Rule, the LGMA will be able to compare and contrast its standards with the federal requirements. For the time being, the Metrics include standards for soil amendments that are more rigorous than the Rule, with the exception of having acceptance criteria for LM.

Animals

FDA Produce Rule	LGMA Metrics
112.83: What requirements apply regarding grazing animals, working animals and animal intrusion? (a) You must take these steps…if there is a reasonable probability that grazing animals, working animals or animal intrusion will contaminate covered produce: (b) You must: (1) Assess the relevant areas…for evidence of potential contamination… (2) If significant evidence…is found…evaluate whether the covered produce can be harvested in accordance with the requirements of 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify and not harvest covered produce that is likely to be contaminated with known or reasonably foreseeable hazard.	3.1 – Environmental assessments shall be "completed and documented prior to the first seasonal planting, within one week prior to harvesting and during harvest operations." Focus these assessments on evaluating the production field for possible animal hazards or other sources of human pathogens of concern, assessing adjacent land uses for possible sources that might contaminate the production field, and evaluating nearby water sources for the potential of past or present flooding. Assessment of Produce Field • Evaluate all produce fields for evidence of animal hazards and/or feces. If any evidence is found, follow procedures identified in the "Production Locations - Encroachment by Animals and Urban Settings." Assessment of Adjacent Land Use • Evaluate all land and waterways adjacent to all production fields for possible sources of human pathogen of concern. These sources include, but are not limited to manure storage, compost storage, CAFO's, grazing/open range areas, surface water, sanitary facilities, and composting operations (see Table 6 for further detail). If any possible uses that might result in produce contamination are present, consult with the metrics and refer to Appendix Z. Assessment of Historical Land Use • To the degree practical, determine and document the historical land uses for production fields and any potential issues from these uses that might impact food safety (i.e., hazardous waste sites, landfills, etc.). Assessment of Flooding • Evaluate all produce fields for evidence of flooding. If any evidence is found, follow procedures identified in the "Flooding" section below.

Implications

<u>In the Metrics but not in the Produce Rule</u>:

- The Metrics require three environmental assessments for each leafy greens ranch (prior to planting, one week prior to harvest, and on the day of harvest).

- Environmental assessments also address flooding, human encroachment, and other potential food safety risks.

In the Produce Rule but not in the Metrics:

- Nothing

The Metrics are more comprehensive and specific regarding animal intrusion hazards presented by environmental risks and methods for mitigating risks.

FDA Produce Rule	LGMA Metrics

112.111: What measures must I take if I grow, harvest, pack or hold *both* covered and excluded produce?
(a) keep covered produce separate from excluded produce…;
 	
(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using …for covered produce
	8.1 – Harvest Equipment
	• Prepare an SOP for harvest equipment that addresses the following:
	  ○ Sanitation verification
	  ○ Daily inspection
	  ○ Proper cleaning, sanitation and storage of hand harvest equipment (knives, scythes, etc.)
	  ○ Control procedures when equipment is not in use, including policy for removal of equipment from the work area or site and the use of scabbards, sheathes or other storage equipment.
	• Design equipment to facilitate cleaning by using materials and construction that facilitate cleaning and sanitation of equipment food contact surfaces (e.g., transportation tarps, conveyor belts, etc.).
	• Establish the frequency of equipment cleaning and sanitation by developing Sanitation Standard Operating Procedures (SSOPs) and a sanitation schedule for machine harvest operations.
	• Evaluate the use of cleaning verification methods for harvesting equipment (e.g., ATP test methods).

112.112: What measure must I take immediately prior to and during harvest activities?
 	
You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated…and not harvest produce that is visibly contaminated with animal excreta. At minimum…requires a visual assessment of the growing area and all covered produce to be harvested…
	Table 5:
	
	Pre-Harvest Assessment and Daily Harvest Assessment: Conduct the daily harvest assessment on each day of harvest.
	• If evidence of medium/high hazard risk animal intrusion into the production block is not discovered until harvest operations:
	  ○ Stop harvest operations.
	  ○ Initiate an intensified block assessment for evidence of further contamination and take appropriate actions per the aforementioned actions.
	  ○ If evidence of intrusion is discovered during production block harvest operations and the harvest rig has been potentially contaminated by contaminated product or feces, clean and sanitize the equipment before resuming harvest operations.
	  ○ Require all employees to wash and sanitize their hands/gloves before resuming harvest operations.

	○ If contamination is discovered in harvest containers such as bins/totes, discard the product, and clean and sanitize the container before reuse.
112.113: How must I handle harvested covered produce during covered activities? You must handle…in a manner that protects against contamination with…hazards. For example, by avoiding…contact of cut surfaces…with soil.	8.1 – Harvest Equipment Establish appropriate measures that reduce and control the potential introduction of human pathogens at the cut surface during and after mechanical harvest operations. Due to the cut surface being more vulnerable to microbial contamination, this best practice is extremely important and all practical means should be taken to reduce the possibility of introduction of contamination at this process step.
112.114: …dropped covered produce. You must not distribute dropped covered produce…	8.1 Prepare an SOP for handling and storage of product containers that addresses the following: • Contact with the ground
112.115: …Packaging covered produce: You must package covered produce in a manner that prevents the formation of clostridium botulin…if such toxin is a known or reasonably foreseeable hazard…	*Clostridium botulinum* has not been associated with leafy greens' harvest and in-field packing activities.
112.116: …Using food-packing (including food packaging) material: (a) Use material that is adequate for its intended use, includes being: (1) cleanable or designed for single use (2) unlikely to support growth or transfer of bacteria (b) If you reuse food-packing material, take adequate steps to ensure that food contact surfaces are clean…	8.1 Prepare an SOP for handling and storage of product containers that addresses the following: • Overnight storage • Contact with the ground • Container assembly (RPC, fiber bin, plastic bin, etc.) • Damaged containers • Use of containers only as intended

Implications

<u>In the Metrics but not in the Produce Rule</u>:

- More detailed sanitation requirements

<u>In the Produce Rule but not in the Metrics</u>:

- Growers must keep covered produce separate from excluded produce (LGMA Metrics apply to all products grown and harvested on the farm)

- Package in a manner that prevents *clostridium botulin*, if a known or reasonably foreseeable hazard (not applicable to leafy greens)
- Use food-packing material that is unlikely to support growth or transfer of bacteria

With the possible exceptions of the items listed above, the LGMA Metrics meet or exceed all requirements in this section. There is probably no reason to add language related to covered produce, as the Metrics cover *all* products grown on covered farms. And *clostridium botulin* is not known to be a hazard on leafy greens farms. More specific packaging requirements should perhaps be considered.

Equipment, Tools, Buildings & Sanitation

FDA Produce Rule	LGMA Metrics
112.121: What equipment and tools are subject to the requirements…? …Those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the grown of microorganisms of public health significance. Examples include knives, implements mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food packing material, dump tanks, flumes and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce.	Scope (Pg. 11): Lettuce/leafy greens may be harvested mechanically or by hand and are almost always consumed uncooked or raw. Because lettuce/leafy greens may be hand-harvested and hand-sorted for quality, there are numerous "touch points" early in the supply chain and a similar number of "touch points" later in the supply chain as the products are used in foodservice or retail operations. Each of these "touch points" represents a potential opportunity for cross-contamination. For purposes of this document, a "touch point" is any occasion when the food is handled by a worker or contacts an equipment food contact surface.
112.122: What buildings are subject to the requirements…? (a) any fully or partially enclosed building used for covered activities, including minimal structures that have a roof but do have any walls; and (b) storage sheds, buildings or other structures used to store food contact surfaces…	*The Metrics apply to the growing and harvesting of leafy greens and transportation to the cooler.*
112.123: General requirements regarding equipment and tools… (a) …use equipment and tools that are of adequate design, construction and workmanship to enable them to be adequately cleaned and maintained… (b) Equipment and tools must be: (1) Installed and maintained to facilitate cleaning… (2) Stored and maintained to protect produce from being contaminated…and to prevent…from attracting and harboring pests. (c) Seams on food contact surfaces…and tools…must be smoothly bonded or maintained to minimize accumulation of dirt, etc.	When farm equipment has had direct contact with raw untreated manure, untreated compost, waters of unknown quality, animals or other potential human pathogen reservoirs it may be a source of cross contamination. Such equipment should not be used in proximity to or in areas where it may contact edible portions of lettuce and or leafy greens without proper sanitation • Segregate equipment used in high-risk operations or potentially exposed to high levels of contamination. • Use effective means of equipment cleaning and sanitation before subsequent equipment use in lettuce/leafy greens production, if it was previously used in a high-risk operation.

(d) (1) …inspect, maintain and clean and sanitize all food contact surfaces…as frequently as reasonably necessary… (2) Maintain and clean all non-food-contact surfaces of…as frequently as reasonably necessary… (e) Use equipment such as pallets, forklifts, tractors and vehicles…in a manner that minimizes the potential for contamination…	• Develop appropriate means of reducing and controlling the possible transfer of human pathogens to soil and water that may directly contact edible lettuce/leafy green tissues through use of equipment. • Maintain appropriate records related to equipment cleaning and possible cross-contamination issues for a period of two years.
112.124: …instruments and controls used to measure, regulate or record… Instruments...must be: (a) accurate and precise…in keeping with their purpose (b) adequately maintained; and (c) adequate in number for their designated uses	*Instruments are not specifically addressed in the LGMA Metrics.*
112.125: …equipment that is…used in the transport of covered produce. Such equipment must be: (a) Adequately clean before use in transporting produce; and (b) Adequate for use in transporting produce	Identify any field operations that may pose a risk for cross-contamination. These include management personnel in the fields, **vehicles used to transport workers**, as well as many other possibilities. • Segregate equipment used in high-risk operations or potentially exposed to high levels of contamination. • Use effective means of equipment cleaning and sanitation before subsequent equipment use in lettuce/leafy greens production, if it was previously used in a high-risk operation. • Develop appropriate means of reducing and controlling the possible transfer of human pathogens to soil and water that may directly contact edible lettuce/leafy green tissues through use of equipment. • Maintain appropriate records related to equipment cleaning and possible cross-contamination issues for a period of two years
112.126: …Buildings (a) All of the following requirements apply: (1) Buildings must be suitable in size, construction and design to facilitate maintenance and sanitary operations… (i) Provide sufficient space for placement of equipment and storage of materials (ii) Permit proper precautions…to reduce the potential for contamination...Potential for contamination must be reduced by effective design including separation of operations in which contamination is likely to	*The Metrics apply to the growing and harvesting of leafy greens and transportation to the cooler.*

occur, by…location, time, partition, enclosed systems, or other effective means, and… (2) Provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor… (b) Implement measure to prevent contamination …considering the potential for such contamination through: (1) Floors, walls, ceilings, fixtures, ducts or pipes; and (2)Drip or condensate	
112.127: …Domesticated animals in and around a fully-enclosed building (a) …Take reasonable precautions to prevent contamination…from animals by: (1) Excluding domesticated animals from…buildings where produce…is exposed; or (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on produce by location, time or partition. (b) Guard or guide dogs may be allowed in some areas…if the presence of the dogs is unlikely to result in contamination…	14.1 – Production Locations • Locate production blocks to minimize potential access by animals and maximize distances to possible sources of microbial contamination. For example, consider the proximity to water (i.e., riparian areas), animal harborage, open range lands, non-contiguous blocks, urban centers, etc. • Periodically monitor these factors and assess during pre-season and pre-harvest assessments as outlined in Tables 5 and 6. If the designated food safety professional deems that there is the potential for microbial contamination from adjacent areas, a risk assessment shall be performed to determine the risk level as well as to evaluate potential strategies to control or reduce the introduction of human pathogens. • DO NOT harvest areas of fields where unusually heavy activity by animals has occurred. If animal intrusions are common on a particular production field, consider fencing, barriers, noisemakers, and other practices that may reduce intrusions. • Train harvest employees to recognize and report evidence (e.g., feces) of animal activity. • Consider controlling risks associated with encroachment by urban development. Risks may include, but are not limited to, domestic animal fecal contamination of production fields and harvest equipment and septic tank leaching. TABLE 6. CROP LAND AND WATER SOURCE ADJACENT LAND USE: Grazing Lands/Domestic Animals (includes homes with hobby farms, and noncommercial livestock): • 30 ft. from the edge of crop. Homes or other building with a septic leach field: • 30 ft. from the edge of crop to the leach field.

112.128: …pest control in buildings (a) …take those measures reasonably necessary to protect covered produce, contact surfaces and materials from contamination by pests in buildings, including routine monitoring… (b) For fully enclosed buildings, take measure to exclude pests… (c) For partially enclosed buildings, take measures to prevent pests form becoming established…	*The Metrics apply to the growing and harvesting of leafy greens and transportation to the cooler.*
112.129: …Toilet facilities All of the following apply: (as) …provide personnel with adequate, readily accessible toilet facilities… (b) …facilities must be designed, located and maintained to: (1) Prevent contamination…with human waste (2) Be directly accessible for servicing, be served and cleaned at a frequency sufficient to ensure suitability of use, and kept supplied with toilet paper; and (3) Provide for the sanitary disposal of waste and toilet paper (c)…you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet to wash their hands **112.130**: …hand-washing facilities All of the following apply: (a) …provide personnel with adequate, readily accessible and washing facilities… (b) …facilities must be furnished with: (1) Soap (2) Running water… (3) Adequate drying devises (such as towels, sanitary service or electric) (c) …Provide for appropriate disposal of waste… (d) You may not use antiseptic hand rubs as a substitute for soap and water	10.1 – Field and Harvest Personnel A field sanitary facility program (i.e., an SOP) shall be implemented, and it should address the following issues: the number, condition, and placement of field sanitation units, the accessibility of the units to the work area, facility maintenance, facility supplies (i.e., hand soap, water, paper towels, toilet paper, etc.), facility signage, facility cleaning and servicing, and a response plan for major leaks or spills. • Sanitary facilities should be placed such that the location minimizes the impact from potential leaks and/or spills while allowing access for cleaning and service. • The location and sanitary design of toilets and hand wash facilities should be optimized to facilitate the control, reduction and elimination of human pathogens from employee hands. Evaluate the location of sanitary facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination. • Establish the frequency of toilet and hand washing facility maintenance/sanitation. • Establish equipment and supply storage and control procedures when not in use. • Maintain documentation of maintenance and sanitation schedules and any remedial practices for a period of two years.
112.131: …Control and dispose of sewage All of the following apply: (a) Dispose of sewage into an adequate sewage or septic system… (b) Maintain sewage and septic systems in a manner that prevents contamination…	14.1 – Production Locations Consider controlling risks associated with encroachment by urban development. Risks may include, but are not limited to, domestic animal fecal contamination of production fields and harvest equipment and septic tank leaching. Table 6 – Adjacent Land Use Homes or other building with a septic leach field:

(c) Manage and dispose of leakages or spills of human waste in a manner that prevents contamination… (d) After a significant event (such as flooding or an earthquake)…you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate…	• 30 ft. from the edge of crop to the leach field. 12.3 – Flooding Prior to replanting or soil testing, the designated food safety professional for the grower shall perform a detailed food safety assessment of the production field. This designated professional will be responsible for assessing the relative merits of testing versus observing the appropriate time interval for planting, and also will coordinate any soil testing plan with appropriate third-party consultants and/or laboratories that have experience in this type of testing. • Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal, etc.) for potential significant upstream contributors of human pathogens at levels that pose a significant threat to human health. • If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting leafy greens... • Evaluate the field history and crop selection on formerly flooded production ground. • Prevent cross-contamination by cleaning or sanitizing any equipment that may have contacted previously flooded soil…
112.132: …Trash, litter and waste All of the following apply: (a) …convey, store and dispose of trash, litter and waste to: (1) Minimize the potential…to attract or harbor pests; and (2) Protect against contamination… (b) …adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination…	*Not Applicable*
112.133: …Plumbing …must be of an adequate size and design and be adequately installed and minted to: (a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations and for hand washing and toilet facilities (b) Properly convey sewage and liquid disposable waste; (c) Avoid being a source of contamination…and, (d) Not allow back-flow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water…	*Not Applicable*

112.134: …animal excreta and litter from domesticated animals… (a) If you have domesticated animals…you must: (1) Adequately control their excreta and litter; and (2) Maintain a system for control of…excreta and litter	14.1 – Production Locations Evaluate the risk to subsequent crop production or production acreage that has experienced recent postharvest grazing with or by domesticated animals that used field culls as a source of animal feed. • Locate production blocks to minimize potential access by animals and maximize distances to possible sources of microbial contamination. For example, consider the proximity to water (i.e., riparian areas), animal harborage, open range lands, non-contiguous blocks, urban centers, etc. Periodically monitor these factors and assess during pre-season and pre-harvest assessments as outlined in Tables 5 and 6. If the designated food safety professional deems that there is the potential for microbial contamination from adjacent areas, a risk assessment shall be performed to determine the risk level as well as to evaluate potential strategies to control or reduce the introduction of human pathogens *Note: Under the Metrics, domestic animals are considered as risk equivalent to any animal intrusion, so are included in and noted during a risk assessment.*

Implications

<u>In the Metrics but not in the Produce Rule</u>:

- More specific language related to sanitation of tools, harvest equipment and animals in the vicinity of growing areas

<u>In the Produce Rule but not in the Metrics</u>:

- Requirements related to fully or partially-enclosed buildings, related to:
  - Size and construction
  - Storage of materials
  - Pest control
  - Trash, litter and waste
  - Plumbing
- Requirements for instruments and controls use to measure, regulate or record

Where the Rule is applicable (i.e., sanitary units, equipment, tools, etc.) the Metrics meet or exceed the requirements. Since fully enclosed buildings are not covered under the LGMA, the Rule's requirements in this area are not considered applicable. The Metrics do not include requirements for instruments; this may need to be considered moving forward.

Summary/Conclusions

The LGMA's Good Agricultural Practices (Metrics) align closely with the Produce Rule. They cover the same risk areas and, in many areas, are more restrictive than the federal standards. This is particularly true in the areas of soil amendments, environmental assessment, worker hygiene and animal intrusion.

However, gaps exist that should be considered, including:

1. *Training*. The Rule requires specific and comprehensive training for workers. While the Metrics require that employees receive appropriate training, the LGMA will need to consider adopting amended language in order to align with the Rule.

2. *Water*. While there are many similarities between the Metrics and the Rule in the area of testing, there are some differences. In particular, the Rule includes concepts not included in the Metrics that provide growers with flexibility in meeting the new water testing and quality requirements. These include creating a Microbial Water Quality Profile (MWQP), establishing a Statistical Threshold Value (STV) and providing a provision for microbial die-off. However, the testing required in the Metrics is generally more rigorous than the Rule. The Metrics require monthly testing, as compared to four (surface water) or one (groundwater) annual test(s) under the Rule. The LGMA allows a single test to exceed the 126 CFU standard, not to exceed 235 MPN, whereas the Rule allows an STV of 410 CFU. And the Metrics do not allow for a die-off period, if water has been used that exceeds the allowable limits. Finally, the Metrics require all water used in the production of leafy greens to be tested, not just water that touches the crop ("Agricultural water").

   It is reasonable to conclude that the Metrics exceed the federal requirements for water testing, and to maintain that growers who comply are also in compliance with the Rule. The question is how important the FDA considers some of the concepts it has introduced in the Rule to be to a rigorous food safety protocol – if the agency feels that Water Quality Profile (WQP) is important, then the LGMA may need to consider including that requirement in the Metrics, possibly basing it on the current level of testing in the program.

   Finally, the water testing method identified in the Rule (membrane filtration) presents challenges for many in the industry, and is not considered an industry standard.

3. *Buildings*. The Rule includes standards that apply to fully enclosed buildings. Since leafy greens production in California generally does not include packing houses or other on farm facilities, and since processing facilities are subject to the Preventive Practices Rule, the Metrics are silent on many of the requirements related to buildings.

4. *Isolated Standards/Practices*. There are instances where the Metrics do not specifically include language or practices covered by the Rule. Examples include some elements of the pre-season water inspection, testing instruments and requirements for packaging materials. These issues can be addressed on a case-by-case basis to determine whether the Metrics should be updated or amended to include them.

Acknowledging these exceptions, it is clear that the Metrics are very closely aligned with the Produce Rule, and are more restrictive overall. Growers subject to the LGMA program can be confident that they also comply with the Rule.

Moving forward, the LGMA, its members, Western Growers, and other stakeholders will further analyze these requirements, and consider those changes to the Metrics needed to ensure that compliance with the LGMA means compliance with the Produce Rule.